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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/587,653	06/05/2000	David V. Sangar	UTSG.231US	8912

7590 11/28/2005

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EXAMINER	
LI, BAO Q	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/587,653	SANGAR ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/26/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-21,27-33 and 51-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-21,27-33 and 51-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment and argument

The amendment filed 03/30/05 has been acknowledged. Claims 1-18, 22-26, 34-50 have been canceled in the amendment. Claims 19-21, 27-33 and 51-56 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Sequence requirements

This application contains sequence disclosure in **line 5 of page 33** that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

2. The later-filed application must be an application for a patent for an invention, which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35

U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

3. The disclosure of the prior-filed application, the provisional Application No. 60,137,665, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Therefore, since claims 51-55 lack support from the provisional application No. 60,137,665, the priority of the claims 51-55 is therefore, considered to be the filing date of current application on June 05, 2000, whereas the priority of rest claims 19-21, 27-33 and 56 is the date of filing date of the provisional application No. 60,137,665 on June 04, 1999.

New ground rejections:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 19-21, 27-33 and 51-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The claim 19 is also vague in that the use of a relative term of "derived". Since the specification does not provide a standard for ascertaining the requisite degree of derivation and the term of "GBV-B derived virus" has many interpretations, one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. Furthermore, claim 19 is vague and indefinite in that the metes and bounds of "a GBV-B derived virus" are neither defined neither by the specification nor by the claim itself. Therefore the claim is considered as indefinite. This affects the dependent claims 20-21, 27-33 and 51-56.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 19-20, 27-33, 51-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling to isolate an infectious GBV-B virus encoded by the full length of the virus DNA of SEQ ID NO: 2, which has the full length of 3' terminal sequence of SEQ ID NO: 1, wherein the method comprises injecting said virus genome in full length into liver of tamurin to produce infectious GBV-B virus clone, does not provide enablement for any person skilled in the art to have a method comprising administering into any kind of host cell a fragment comprising any 50 or 100 continuous nucleotides of 3' terminal sequence of GBV-B viral sequence, SEQ ID NO: 3 optionally plus any 250 to 500 contiguous nucleotides of SEQ ID NO: 2 of said virus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

6. The test of scope of the enablement is whether one skilled in the art could make and use the claimed invention from the disclosure in the application coupled with information known in the art would undue experimentation (See United States v. Theketronic Inc., 8USPQ2d 1217 (fed Cir. 1988). Whether undue experimentation is required is not based upon a single factor but rather a conclusion reached by weighting many factors. Theses factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in re Wands, 8USPQ2d 1400 (Fed. Cir. 1988). These factors include, but are not limited:

7. A). The nature of the invention; B). The breadth of the claims; C). The state of art; D). The predictability of the art; E). The level of one of ordinary skilled in the art; F). The amount of direction provided by the inventor; G). The existence of working example.

8. In the instant case, the nature of the invention is a method for producing a recombinant GBV-B virus by introducing a recombinant GBV-B virus RNA genome into a susceptible host cell of a susceptible animal, culturing said host cell and isolating said virus from said host cell; wherein the recombinant GBV-B virus comprises a particular 3' terminal sequence of GBV-B of SEQ ID NO: 1. The broad scope of the claims read on using any recombinant virus genome as

lone as it comprises at least 50 contiguous nucleotides from the SEQ ID NO: 1, and the host cell can be used with any kind of prokaryotic or eukaryotic cell as well as any animal.

9. The state of art teaches that GB virus B (GBV-B) is the most closely related virus to the hepatitis C virus (HCV) and is an attractive surrogate model system for HCV replication and drug development. Unfortunately, GBV-B can only be grow in the primary hapatocytes or certain non-human primates as evidenced by Buckwold et al. (Antiviral Research 2005, Vol. 66, pp. 165-168). Buckwold et al. teach that while an infectious GBV-B RNA could be transfected into Vero, Huh7 and HepG2 at high efficiency, however, there was no evidence for GBV-B replication in such cell lines (See abstract). Therefore, it is very unpredictable for producing any GBV-B recombinant virus with any or all kind of host cells or hosts.

10. While specification teaches several chimeric GBV-B virus made by insertion HCV non-structural proteins into the background of GBV-B backbone; the all recombinant GBV-B/HCV chimeric virus produced contain the full length 3' terminal 259 nucleotides, and the infectious clone of GBV-B virus is produced by introducing the full length of said viral gene into liver of tamarin. There is no teach which 50-100 contiguous nucleotides of SEQ ID NO: 1 can be used for producing a GBV-B virus, and which optionally 250-5000 of SEQ ID NO: 2 are required. The specification does not teach a method for producing and isolating a recombinant GBV-B virus from a cell o from any animal. The specification lacks sufficient evidence to support the broad scope of claimed invention.

11. Because there is still unknown why the GBV-B virus can only effectively replicate in the non-human primate tamarin and tamarin liver cell, the level of skill to use any or all host cell or host to produce GBV-B recombinant virus or any virus with only partial sequences of SEQ ID NO: 1 and 2 are high and also involve undue experimentation.

12. Given the above analysis of the factors which the courts have determined are critical in asserting whether a claimed invention is enabled, it must be considered that the skilled artisan would have had to have conducted undue and excessive experimentation in order to practice the claimed invention.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

14. Claims 19-20, 28-33, 51-54 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Traboni C. (US patent No. 6,627,437B1) in light of disclosure by Sbardellati et al. (J Gene. Virol. 2001, Vol. 82, pp. 2437-2448).

15. Traboni C teaches a method for producing an infectious GBV-B virus. The method comprises transcribing the full length cDNA of a GBV-B virus and injecting the transcript into the livers of tamarins to produce the infectious GBV-B virus that comprise the 3' terminal sequence comprising at least 100 contiguous nucleotides to the claimed 3' terminal RNA molecule of SEQ ID NO: 1. Furthermore, the coda used for transcribing the full length infectious GBV-B viral genome deposited under the accession number AJ277947 (line 16-18 on column 19), which inherently comprise at least 250 to 5000 contiguous nucleotide of claimed GBV-B viral DNA sequence of SEQ ID NO: 2 in light of the disclosure by Sbardellati et al. (J. Gene. Virol. 2001, Vol. 82, pp. 2437-2448, see bottom of column 1 of page 2437 and NCBI AJ277947 page 1-5). Therefore, the claimed invention is anticipated by the cited reference.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

17. Claim 51-54 are rejected under 35 U.S.C. 102(a) as being anticipated by Bukh et al. (Virol. Sept. 1999, Vol. 262, No. 2, pp. 470-478).

18. Bukh et al. disclose a hepatitis GB virus-B, wherein the virus genome is encoded by 9399 nucleotides sequence comprising at least 250 to 500 contiguous nucleotides of the claimed nucleotide sequence of SEQ ID NO: 2. They also disclose to use said virus to infect tamarins for producing the infectious virus clone. Therefore, the claimed invention is anticipated by the cited reference (See the entire document and sequence comparison analysis).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li 11/23/2005

BAOQUN LI, MD
PATENT EXAMINER